EAN 8721008158181
SOA Test - Compleet (Vaginaal)

Product foto

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HOLOGIC

Hologic San Diego Collection, Transport and Lysis Kits
Declaration of Conformity

SIGNATURES ON FILE

Object of the Declaration:

Registered Name	Catalog No.	Basic UDI-DI
Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens	301040	54200455DIAGCOLLECTVT
Aptima Specimen Transfer Kit / Aptima Specimen Transfer Kit - Printable	301154C / PRD-05110	
Aptima Urine Specimen Transport Tubes	105575	
Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens	301041	
Aptima Cervical Specimen Collection and Transport Kit	302657	
Aptima Multitest Swab Specimen Collection Kit	PRD-03546	
Rapid fFN Test Specimen Collection Kit	PRD-01020	
Panther Fusion Specimen Lysis Tubes	PRD-04339	
Hologic Specimen Lysis Tubes	PRD-06554	
Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs	PRD-06951	
Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs	PRD-06952	

Technical File Reference: TFS-00020

Manufacturer's Name and Address: Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA

Manufacturer's SRN: US-MF-000001646

Authorized Representative: Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

Authorized Representative SRN:	BE-AR-000000127
Conformity Assessment Procedure:	Self-Certified; Annex II and III
Classification/ Conformity Assessment:	Class A *in vitro* diagnostic device per Rule 5, Annex VIII of EU 2017/746
EC Certificate No. / EC Certificate Expiration Date:	Not Applicable

Intended Purpose:

The Hologic SD Collection, Transport and Lysis Kits consist of a variety of kits containing multiple devices intended to be used as specimen receptacles for the collection and transport or lysing of human biological specimens. The specimens collected are intended to be used with various Hologic diagnostic/screening assays.

Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens

The Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens is for use with Aptima assays. The Aptima Urine Specimen Collection Kit is intended to be used for the collection and transport of male or female urine specimens.

Aptima Specimen Transfer Kit / Aptima Specimen Transfer Kit – Printable

The Aptima Specimen Transfer Kit consists of transfer tubes containing Specimen Transport Medium (STM) and is intended for use with liquid specimen media to enable testing with Aptima assays and other Hologic products. The Aptima Specimen Transfer Kit allows for Aptima HPV assay and Aptima HPV 16 18/45 genotype assay testing of gynecological specimens collected in ThinPrep Pap Test vials containing PreservCyt solution, and specimens collected in SurePath Preservative Fluid treated with Aptima Transfer Solution. The Aptima Specimen Transfer Kit may also be used to enable testing of viral transport media (VTM) containing lesion swab specimens. Refer to the appropriate Hologic product package insert for the indicated uses of the Aptima Specimen Transfer Kit for each product.

Aptima Urine Specimen Transport Tubes

The Aptima urine specimen transport tubes are for use with Aptima assays. The Aptima urine specimen transport tube is intended to be used for the collection and transport of male or female urine specimens.

Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens

The Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens is for use with Aptima assays. The Aptima Unisex Swab Specimen Collection Kit is intended to be used for the collection of female endocervical or male urethral swab specimens. The Aptima Unisex Swab Specimen Collection Kit is also intended for use with other clinical specimen material for processing, extraction, and analysis with other Hologic products as specified in their labeling.

Aptima Cervical Specimen Collection and Transport Kit

The Aptima Cervical Specimen Collection and Transport Kit is intended to be used for clinician collection and transport of cervical specimens for use with the Aptima HPV Assay and Aptima HPV 16/18/45 Genotype Assay. Refer to the appropriate assay package inserts for additional assay specific information related to the Aptima Cervical Specimen and Transport Kit.

Aptima Multitest Swab Specimen Collection Kit

The Aptima Multitest Swab Specimen Collection Kit is intended to be used for collection of the following swab specimen types: vaginal, rectal, throat, penile meatal, and lesions. Refer to the appropriate assay package insert for appropriate specimen types. *Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The Aptima Multitest Swab Specimen Collection Kit has not been evaluated for home use. The Aptima Multitest Swab Specimen Collection Kit for Multitest Swab Specimens is also intended for use with other clinical specimen material for processing, extraction, and analysis with other Hologic products as specified in their labeling.

*Note: Patient Collection may also be available depending on the particular assay that the kit is being used with. Refer to the appropriate assay package insert.

Aptima® Multitest Swab Specimen Collection Kit for SARS-CoV-2 Specimen Collection

The Aptima® Multitest Swab Specimen Collection Kit is intended to be used for clinician collection of throat and nasal swab specimens and patient collection of nasal swab specimens in a healthcare setting for testing with Hologic assays to detect the presence of RNA for SARS-CoV-2 and other respiratory viruses.

Rapid fFN Test Specimen Collection Kit

The Rapid fFN Test Specimen Collection Kit contains specimen collection devices consisting of a sterile, polyester-tipped swab and a specimen transport tube containing 1 ml extraction buffer. This specimen collection device is intended for collection of cervicovaginal specimens for the Rapid fFN Tests (Perilynx System, Rapid fFN 10Q System). Specimens should be obtained only during a speculum examination.

Panther Fusion Specimen Lysis Tubes

Specimen Lysis Tubes are intended to be used for processing specimens for use with Hologic assays. Refer to the applicable assay package insert for appropriate Specimen Lysis Tubes and specimen types authorized for use with each assay.

Hologic Specimen Lysis Tubes

Specimen Lysis Tubes are intended to be used for processing specimens for use with Hologic assays. Refer to the applicable assay package insert for appropriate Specimen Lysis Tubes and specimen types authorized for use with each assay.

Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs

The Hologic Direct Load Capture Cap Collection Kit – CLASSIQSwabs is intended to be used for clinician collection of OP and nasal swab specimens and patient collection of nasal swab specimens in

a health care setting for testing with Hologic assays to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A) and/or influenza B virus (Flu B).

Hologic Direct Load Capture Cap Collection Kit - FLOQSwabs

The Hologic Direct Load Capture Cap Collection Kit – FLOQSwabs is intended to be used for clinician collection of mid-turbinate and nasopharyngeal (NP) swab specimens for testing with the Aptima SARS-CoV-2 assay to detect the presence of RNA for SARS-CoV-2. The kit is also intended to be used for clinician collection of NP swab specimens for testing with the Aptima SARS-CoV-2/Flu assay to detect the presence of RNA for SARS-CoV-2, influenza A virus (Flu A) and/or influenza B virus (Flu B).

Declaration of Conformity to Standards:

The devices covered by the present declaration are in conformity with the European Union (EU) in vitro Diagnostics Regulation (IVDR 2017/746), and, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. The object of the declaration described above is in conformity with the requirements of the following standards:

Standard	Revision	Title
EN ISO 18113-1	2011	In Vitro Diagnostic Medical Devices Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions, and general requirements.
EN ISO 18113-2	2011	In Vitro Diagnostic Medical Devices Information supplied by the manufacturer (labeling) - Part 2: IVD reagents for professional use
EN ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purposes
EN ISO 13612	2002	Performance evaluation of in vitro diagnostic medical devices
ASTM D4169-92A	2016	Standard Practice for Performance Testing of Shipping Containers and Systems

Standard	Revision	Title
EN ISO 23640	2015	In vitro diagnostic medical devices – Evaluation of stability of in-vitro diagnostic reagents
EN 62366-1	2015+AMD1:2020	Medical Devices-Application of usability engineering to medical devices
EN 13975	2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices – Statistical aspects
ISO 2859-1 *	1999	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
EN ISO 14971	2019	Medical devices-Application of risk management to medical devices
BS EN 13641	2002	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices

* **Please note:** ISO 2859-1: 1999 is followed by the Hologic Direct Load Capture Cap Collection Kit CLASSIQSwabs and the Hologic Direct Load Capture Cap Collection Kit- FLOQSwabs instead of BS EN 13975:2003

This EC declaration of conformity is issued under the sole responsibility of Hologic, Inc.

Signed for and on behalf of Hologic, Inc.

Jill Wyland — San Diego, CA, US — May 25, 2022

Name / Title: Jill Wyland / Director, Regulatory Affairs — Place / Date

Revision History:

Revision	Version/History Description	Issue Date	Regulatory Author
001	Initial Release	5/4/2022	Bryce Dzialo